consisting of said first axial end of said tubular graft, said second axial end of said stent and adhesive fixedly connecting said graft and said stent.

27. An endovascular stent/graft assembly comprising a tubular graft having first and second axial ends and a passage extending between the ends, a stent having first and second axial ends and a passage extending between the ends, said first axial end of said tubular graft being connected substantially in end-to-end relationship with said second axial end of said stent to define a connection, said connection consisting of said first axial end of said tubular graft, said second axial end of said stent and sutures for fixedly connecting the first axial end of the tubular graft to the second axial end of the stent.

REMARKS

Reconsideration of this application, as amended, is requested.

Claims 2-4 and 25-27 remain under consideration in this application. Claim 1 has been cancelled in favor of new independent claim 25. New independent claims 26 and 27 also have been added. Claims 2-4 have been amended to depend from and conform with new independent claim 25. Claims 5-24 remain currently withdrawn from consideration in view of the election that was noted in the Office Action.

Counsel wishes to think Examiner Blanco and Supervisory Patent Examiner McDermott for the courtesies extended during the interview on October 31, 2002. Counsel had sent the Examiners a proposed amendment prior to the interview, and the proposed amendment was discussed during the course of the interview. The Examiners stated that the term "end" employed in both the original claims and in the proposed amendment could be interpreted as being a location on the stent or the graft intermediate the length of the stent or the graft. Accordingly, the

Examiners suggested that counsel and the applicant consider defining the ends more clearly to distinguish over the prior art. The Examiners had no specific recommendation for terms that could be incorporated into the claims, but suggested that the applicant might consider the term "distal".

The terms "distal" and "proximal" often are used together in medical literature. The term "proximal" generally refers to an end of an object closer to the center of a body, while the term "distal" generally refers to the end of an object farther from the center of the body. Thus, the hip is at the "proximal" end of the femur, whereas the knee is at the "distal" end of the femur. Patent practitioners often use the term "distal" in a different context to define "the" end, and not a region near "the" end. Counsel considered the Examiners' suggested terminology of "distal" for defining the ends of the graft or stent of the subject invention. However, it is believed that use of the term "distal" could lead to confusion in the context of the subject application. If the term "distal" were employed to define the connected portions of the graft and the stent then conventional medical use of these terms would suggest that the graft and the stent extended in the same direction from their connected "distal" ends and that their "proximal" ends might be coincident. This terminology would seem to cover the admitted prior art described on page 2 of the application. Counsel had considered using both "proximal" and "distal" to define the connected ends. However, this usage of terms would require a specific orientation of the graft and the stent relative to the center of the body. In addition to the preceding problems, the original specification did not use the term "proximal" and/or "distal" in the context suggested by the Examiners. Counsel has concluded that the term "axial" provides the precision requested by the Examiners and is supported by the original specification. An axial end of a tubular object clearly is not an end region somewhere along the length the tubular object. Thus, the claims

axial end

submitted herein differ from the claims discussed during the interview in that the ends of the graft and the stent are defined as being "axial ends".

In reviewing the attached amendment, counsel also determined that the reference in the preamble of proposed new independent claim 25 to a "damaged section" of a blood vessel did not have proper support in the original specification. Accordingly, the attached amendment defines the endovascular stent/graft assembly as being "for repairing a section of a blood vessel that has an aneurysm." Thus, independent claim 25 clearly is supported by the specification.

This Amendment is submitted concurrently with the Request for Approval of Drawing Changes. The Request is accompanied by a copy of the sheet of drawings that present FIGS. 4 and 5. The curved hooks depicted originally in FIGS. 4 and 5 now have been supplemented with the number 28 as presented in the original specification. Formal drawings will be filed upon allowance of the claims.

The Examiner raised a formal objection to claim 2. The amendments to claim 2 address this rejection.

Claims 1-4 were rejected under 35 USC 112, second paragraph. The Examiner identified specific objectable terminology in original claims 1 and 2. It is believed that the amended and new claims address the rejection under 35 USC 112, second paragraph.

Claims 1-4 were rejected under 35 USC 102(b) as being anticipated by Frantzen et al. The Examiner identified sections of the Frantzen et al. reference that were considered to support the rejection.

Frantzen et al. is directed to a flexible connection between a stent and a vascular graft. In particular, the Frantzen et al. reference shows an assembly 20 that includes a stent 21, a vascular graft 22 and coupler 10. The stent 21 shown in the

embodiments of FIGS. 3, 4 and 5 is a generally tubular structure that is spaced axially from the tubular graft 22. The embodiment of FIGS. 6 and 7 also has the tubular stent 21 spaced axially from the tubular graft 22. However, the embodiment of FIGS. 6 and 7 further includes a plurality of tabs 27 that bridge the axial gap between the tubular stent 21 and the tubular graft 22. The tabs 27 have T-members at their ends for attachment to the graft 22. All embodiments of Frantzen include and require the coupler 10. The coupler 10 is defined as being formed from an elastic material that can elongate up to 500%. The coupler concentrically surrounds portions of the stent 21 and the graft 22 and bridges the gap between the stent 21 and the graft 22. The high degree of the elasticity of the coupler 10 will permit axial movement between the stent 21 and the graft 22 and circumferential expansion of the coupler 10. The Frantzen et al. disclosure provides no specific explanation of the motive for the particular designs shown therein. However, as explained in the Information Disclosure Statement of August 2, 2002, it appears that the primary objective of the Frantzen et al. device is to prevent blood flow between the graft and the ameurysm. Such a blood flow is referred to as a Type I Endoleak. The coupler 10 of Frantzen et al. resembles a butt joint employed in the repair of a boat hull. More particularly, a traditional butt joint includes two members that have their ends axially aligned and that are overlapped by a supporting structure. The Examiner will appreciate that the Frantzen et al. requirement for a coupler 10 to surround both the stent 21 and the graft 22 will add significantly to the cross-sectional dimensions of the assembly. The coupler 10 also will complicate the insertion and implantation, and will require a larger incision and more trauma for the patient.

In contrast to Frantzen et al., the invention defined by new claim 25 is directed to an endovascular stent/graft assembly with "a stent means for directly contacting said first relatively healthy section of said blood vessel." The stent means is

defined as being substantially tubular and having opposite first and second axial ends. The assembly is further defined as having "substantially tubular graft means having a first axial end, portions of said graft means adjacent said first axial end being for directly contacting said first relatively healthy section of said blood vessel, said first axial end being fixedly connected with the second axial end of the stent means for achieving a substantially end-to-end connection." The graft means further is defined as "having a second axial end for directly contacting said second relatively healthy section of said blood vessel such that portions of said graft means between said first and second axial ends bridge said damaged section of said blood vessel." The Frantzen et al. reference does not have "a substantially tubular graft means having a first axial end for directly contacting said first healthy section of said blood vessel." The first end of the tubular graft 22 of Frantzen et al. could be made to contact the blood vessel only by removing the coupler 10. However, the coupler 10 clearly is essential to the Frantzen et al. device and gives the Frantzen et al. device the elasticity that is clearly essential to the device. Hence, there would be no motivation for a person skilled in the art to remove the essential coupler of Frantzen et al. and to fixedly connect the axial ends of the stent and graft as set forth in new claim 25 and amended dependent claims 2-4. In contrast, the invention of new claim 25 has no coupler and hence has a smaller cross-section, an easier insertion and less trauma for the patient.

New claim 26 defines the stent/graft assembly such that the first end of the tubular graft is connected substantially in end-to-end relationship with the second end of the stent to define a connection. New claim 26 then defines the connection as "consisting of said first axial end of the said tubular graft, said axial second end of said stent and adhesive fixedly connecting said graft and said stent." New claim 27 employs similar terminology, but defines the connection as "consisting of said first axial end of

said tubular graft, said second axial end of said stent and sutures for fixedly connecting the first axial end of the tubular graft to the second axial end of the stent." The "consisting of" terminology employed in new claims 26 and 27 precludes the coupler 10 that is a required element of Frantzen et al. Once again, it is submitted that nothing in the Frantzen et al. reference will lead the skilled artisan to the significant revisions that would be required to bring Frantzen et al. closer to the claimed invention.

In view of the preceding amendments and remarks, it is submitted that the claims remaining in the application are directed to patentable subject matter, and allowance is solicited. The Examiner is urged contact applicant's attorney at the number below to expedite the prosecution of this application.

Respectfully submitted,

Gerald E. Hespos, Esq.
Atty. Reg. No. 30,066
Customer No. 001218
CASELLA & HESPOS LLP
274 Madison Avenue - Suite 1703
New York, NY 10016
Tel. (212) 725-2450
Fax (212) 725-2452

Date: November 5, 2002

"Version with markings to show changes made."

--2. (amended) The endovascular stent/graft assembly of claim [1] 25, wherein the [substantially end-to-end disposition] first axial end of the tubular graft [and the fixation device comprises a sufficient overlap between the ends of the tubular graft and, the fixation device] means is sufficiently overlapped with the second axial end of the stent means to achieve secure affixation between the [fixation device] stent means and the tubular graft means.--

--3. (amended) The endovascular stent/graft assembly of claim [1] 25, wherein the first axial end of the tubular graft means and the second axial end of the [fixat-ion device] stent means are affixed by bonding.--

--4. (amended) The endovascular stent/graft assembly of claim [1] 25, wherein the first axial end of the tubular graft means and the second axial end of the [fixation device] stent means are affixed by sutures.--

FIG. 4

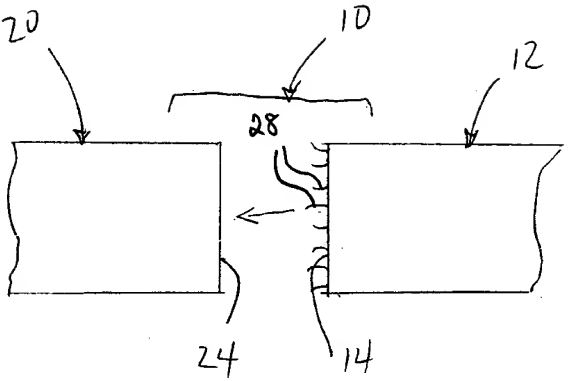

FIG. 5